SI-BONE Complaint Reporting Form

Submission Date	2024-10-01 13:17:24
Your name	Ryan Crowley
Customer name	Trevor McIver
How did you learn about this issue? (select all that apply)?	From the HCP or associated staff
Please provide any relevant details about your communication. Full complaint description will be captured on the following page:	Scheduled as a revision to remove first implant and replace with Torq.
Date you first heard of problem with SI-BONE product.	09-17-2024
Indicate affected device(s) (choose all that apply)	iFuse-3D
Part number(s) (please list the number of each part involved)(required)	7.0x50
Lot number(s)	NA
Did the product complaint result in a patient problem?	YES, potential or actual (Ex: required revision, patient adverse event)
What problem did patient have?	Continued, recurrent, or new pain
Best description of time course of pain recurrence:	Pain got better but then recurred
How long did the patient experience pain relief?	More than 12 months
Were any additional causes of pain discovered during workup?	I don't know
If CT was performed, please email scan to QA@si-bone.com. CT results show:	Inadequate implant engagement in sacrum
Additional CT results / details	Not sure
Was initial surgery attended by SI-BONE staff member?	Yes
Name of SI-BONE staff member attending initial surgery	NA NA
See summary of IFU steps. Did surgeon complete all steps as shown above?	Yes, all steps were completed accurately
Please describe any steps inaccurately performed, or other details of the case	Patient did well after first surgery and returned with SI pain that was confirmed by injection. He wanted to put in a longer Torq implant to help.
Did patient have revision surgery as a result of this problem?	No